

CHAPTER 15
CORRECTIONAL FACILITY PHARMACY LICENSES

657—15.1(124,126,155A) General requirements. It is the intent of this rule to authorize the department of corrections to distribute prescription drugs to inmates in correctional institutions by and through a network of pharmacies licensed by the board with limited-use pharmacy licenses designated as correctional facility pharmacy licenses and located in facilities operated pursuant to Iowa Code chapter 904. Pharmacists shall be responsible for any delegated act performed by supportive personnel under their supervision.

657—15.2(124,126,155A) Sanitation. Drugs shall be stored in a manner to protect their identity and integrity. A sink with hot and cold running water shall be available within the pharmacy and shall be maintained in a sanitary condition at all times.

657—15.3(124,126,155A) Reference library. References may be printed or computer-accessed. Each correctional facility pharmacy shall have on site, as a minimum, one reference from each of the following:

1. Current Iowa pharmacy laws, rules, and regulations.
2. A patient information reference, updated at least annually, such as:
 - United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient);
 - Facts and Comparisons Patient Drug Facts; or
 - Leaflets which provide patient information in compliance with rule 657—8.20(155A).
3. A current reference on drug interactions, such as:
 - Phillip D. Hansten's Drug Interactions; or
 - Facts and Comparisons Drug Interactions.
4. A general information reference, updated at least annually, such as:
 - Facts and Comparisons with current supplements;
 - United States Pharmacopeia Dispensing Information, Volume I (Drug Information for the Health Care Provider); or
 - American Hospital Formulary Service with current supplements.
5. A current drug equivalency reference, including supplements, such as:
 - Approved Drug Products With Therapeutic Equivalence Evaluations (FDA Orange Book);
 - ABC - Approved Bioequivalency Codes; or
 - USP DI, Volume III.
6. Basic antidote information or the telephone number of a poison control center.
7. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—15.4(124,126,155A) Prescription department equipment. Each correctional facility pharmacy shall have on site, as a minimum, the following equipment:

1. Refrigeration unit capable of maintaining temperatures within a range compatible with the proper storage of drugs requiring refrigeration;
2. Graduates capable of measuring 1 ml. to 250 ml.;
3. Other equipment as necessary for the particular practice of pharmacy.
4. Access to a Class A prescription balance sensitive to 10 mg., with weights, shall be available within the network of correctional facility pharmacies where compounding takes place.

657—15.5(124,126,155A) Security. The pharmacist in charge, with the concurrence of the department of corrections, shall establish policies and procedures which identify who will have access to correctional facility pharmacies when the pharmacist is absent and the procedures to be followed for obtaining prescription drugs and chemicals during that absence. In determining the adequacy of security measures, the board will consider the factors outlined in rule 6.6(155A).

15.5(1) All areas occupied by the correctional facility pharmacy shall be capable of being locked by key or combination so as to prevent access by unauthorized personnel.

15.5(2) The pharmacist in charge shall develop and implement policies and procedures for the security of correctional facility pharmacies, including adequate safeguards against theft or diversion of prescription drugs, controlled substances, and records for such drugs. Policies and procedures shall be developed with the approval of the department of corrections.

15.5(3) All drugs distributed from the pharmacy to other areas of the correctional facility for subsequent administration to inmates shall be kept in locked storage when not in use, with access restricted to the medication nurse or qualified designee.

657—15.6(124,126,155A) Procurement and storage of drugs. The pharmacist in charge shall be responsible for the procurement and storage of all drugs.

15.6(1) The pharmacist in charge shall have the responsibility for determining specifications of all drugs procured by the facility.

15.6(2) All drugs shall be stored at the proper temperatures, as defined in the USP/NF.

15.6(3) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

15.6(4) Outdated drugs shall be removed from dispensing stock and quarantined until such drugs are lawfully disposed.

657—15.7(124,126,155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124, 155A, and 205, or board rules, shall be kept by the pharmacy and be available for inspection and copying by the board or its representative and to other authorized local, state or federal law enforcement agencies for at least two years from the date of the inventory or record except as otherwise required in this rule.

15.7(1) “Medication prescription orders” are orders for medication for persons in custody status in a correctional institution, originated by a practitioner authorized to prescribe, which meet the information requirements for a prescription order but are recorded, distributed, and administered as though they were medication orders. Medication prescription orders written in inmate health records shall include the following information:

- a. Inmate name, identification number, and location;
- b. Drug name, strength, dosage form, and quantity or duration;
- c. Directions for use;
- d. Date of issue;
- e. Prescriber’s name or signature and office address if different from that of the correctional facility;
- f. Prescriber’s DEA number for controlled substances if not on file in the correctional facility pharmacy.

15.7(2) The original medication prescription order shall be maintained with the medication administration record in the health record of the inmate for a minimum of two years.

15.7(3) The pharmacist in charge at each correctional facility pharmacy shall determine that combination of manual and computerized records that constitutes a readily retrievable record of drugs dispensed.

15.7(4) Current medication prescription orders remain in effect when an inmate is transferred within the correctional institution system.

15.7(5) Controlled substance records shall be maintained as follows:

- a.* All records for controlled substances shall be maintained in a readily retrievable manner.
- b.* Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances.
- c.* Records of controlled substances in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records.
- d.* Controlled substances which are issued as unit stock shall be accompanied by a proof-of-use form which provides for documentation of the following information:
 - (1) Inmate's name and identification number;
 - (2) Prescriber;
 - (3) Drug name, strength, and dosage form;
 - (4) Date and time of administration;
 - (5) Quantity administered;
 - (6) Name of individual administering the controlled substance;
 - (7) Returns to the pharmacy;
 - (8) Waste, which is required to be witnessed and cosigned by another licensed health professional.
- e.* Invoices involving the distribution of Schedule III, IV, or V controlled substances to another pharmacy or practitioner shall show the actual date of distribution; the name, strength, and quantity of controlled substances distributed; the name, address, and DEA registration number of the distributing pharmacy and of the practitioner or pharmacy receiving the controlled substances.
- f.* Copy 1 of DEA order Form 222, furnished by the pharmacy or practitioner to whom Schedule II controlled substances are distributed, shall be maintained by the distributing pharmacy and shall show the quantity of controlled substances distributed and the actual date of distribution.
- g.* Copy 3 of DEA order Form 222 shall be properly dated, initialed and filed and shall include all copies of each unaccepted or defective order form and any attached statements or other documents.
- h.* If controlled substances, prescription drugs, or nonprescription drug items are listed on the same record, the controlled substances shall be asterisked, red-lined, or in some other manner readily identifiable from all other items appearing on the record.
- i.* Suppliers' invoices of prescription drugs and controlled substances shall clearly record the actual date of receipt by the pharmacist or other responsible individual.
- j.* Suppliers' credit memos for controlled substances and prescription drugs shall be maintained.
- k.* A biennial inventory of controlled substances shall be maintained for a minimum of four years from the date of the inventory.
- l.* Reports of theft or significant loss of controlled substances shall be maintained.
- m.* Reports of surrender or destruction of controlled substances shall be maintained.

657—15.8(124,126,155A) Drug distribution and dispensing. Prescription drugs may be distributed or dispensed only from the original or a properly verified practitioner's order.

15.8(1) Drugs dispensed in a unit dose dispensing system for subsequent administration by nurses or other qualified individuals shall be packaged and labeled in compliance with the provisions of rule 657—23.12(124,126,155A).

15.8(2) Registered nurses may issue an inmate's prepackaged medications from the supply distributed by the pharmacist for that inmate, into envelopes or other appropriate container to facilitate subsequent administration by other qualified individuals. Said qualified individuals shall use the medication administration record, or a properly verified copy thereof, to administer and document administration of those medications to the inmate. The single unit or unit dose packaging shall remain intact to the point of administration.

15.8(3) Drugs dispensed for self-administration by the inmate, either during incarceration or subsequent to the inmate's departure from the department of corrections custody status, shall be packaged and labeled in accordance with rule 657—8.14(155A).

15.8(4) Correctional facility pharmacies shall be exempt from the labeling provisions and patient notification requirements of Iowa Code section 155A.32, as respects drugs distributed pursuant to medication prescription orders.

657—15.9(124,126,155A) Pharmacist in charge. Each correctional facility pharmacy shall have one pharmacist in charge who shall have the responsibility, at a minimum, for the following:

1. Prepackaging and bulk compounding of drugs in compliance with the provisions of rules 657—8.3(126) and 657—20.11(126);
2. Dispensing and distribution of drugs in compliance with the labeling, record keeping, and other requirements of these rules;
3. Quarterly inspection of all pharmaceuticals located at the correctional facility including emergency and provisional stocks located outside the confines of the pharmacy;
4. Records of all transactions of the correctional facility pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain adequate control over, and accountability for, all pharmaceutical materials;
5. Development, implementation, and review of pharmacy policies and procedures consistent with these rules and existing department of corrections policies relating to pharmaceutical services.

657—15.10(124,126,155A) Policies and procedures. Written policies and procedures for the correctional facility pharmacy drug distribution system shall be developed and implemented by the pharmacist in charge of the correctional facility pharmacy consistent with department of corrections policies and procedures pertaining to pharmaceutical services and shall include, but not be limited to, the following:

1. Controlled substances;
2. Formulary or drug list;
3. Stop orders;
4. Drug sample use and distribution;
5. Drug recalls;
6. Outdated drugs;
7. Medication profiles;
8. Inspection of drug inventories;
9. Adverse reaction reports;
10. Furlough or discharge medications;
11. Emergency and provisional stocks of drugs;
12. Drugs brought into the facility;
13. Transfers of drugs between facilities.

657—15.11(124,126,155A) Orders for medication received in the absence of a pharmacist.

15.11(1) "Provisional stock" is a limited inventory of drugs stored outside the confines of the correctional facility pharmacy and accessible to designated health services staff for the purpose of initiating critical medication prescription orders issued during periods when the pharmacist is unavailable.

15.11(2) Whenever prescription drugs or medical devices are obtained in the absence of the pharmacist from the pharmacy or provisional stock, the following is applicable:

a. Access to the pharmacy or provisional stock is restricted to those individuals as specified in rule 15.5(124,126,155A);

b. Prescription and nonprescription drugs may be removed from the pharmacy or provisional stock only in the original manufacturer's container or in a container prepackaged by the correctional facility pharmacy in accordance with rule 657—8.3(126);

c. A record shall be made of all withdrawals by the authorized person removing the drugs, which shall include the following information:

- (1) Name and identification number of inmate;
- (2) Name, strength, dosage form, and quantity of drug removed;
- (3) Date and time of withdrawal of the drug;
- (4) Signature or initials of the authorized person making the withdrawal.

d. The original or properly verified copy of new medication prescription orders shall be left with the record of withdrawal.

657—15.12(155A) Training and utilization of pharmacy technicians. Correctional facility pharmacies utilizing pharmacy technicians shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians. Pharmacy policies shall specify the frequency of review. Technician training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of technician training shall be available for inspection by the board or an agent of the board.

These rules are intended to implement Iowa Code sections 124.303, 124.306, 124.307, 124.308, 126.10, 155A.13, 155A.31, and 155A.32.

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